now been removed from the claim, and it is respectfully submitted that the rejection has been thereby obviated. It is accordingly respectfully requested that the rejection be withdrawn.

Claims 1-38 stand rejected under 35 USC 103(a) as being unpatentable over Heinemann et al. (US 3,885,026) in view of Remington (18th Edition, pages 1633-1647). The Examiner stated, in pertinent part:

> Heinemann et al. teaches a method of preparing a tablet by incorporating volatile solids such as camphor, ammonium bicarbonate, and menthol, into tableting components mixture; after the mixture is compressed into a tablet form, the volatile solids are removed by sublimation (See the abstract, col. 2, lines 7-16; also claims 1-2). Heinemann et al. teaches that volatile solids are employed in a weight ratio of 10-30 percent ()See col. 2, lines 22-25; also claims 3-4).
>
> Heinemann et al. does not teach the wet or dry granulation method being employed. Heinemann et al. does not teach the compression of the tablet after the volatile solids are removed. Heinemann et al. does not teach the employment of a compressive agent into the composition.
>
> Remington teaches that wet and dry granulation method is a well-known, commonly used methods of preparation for tablets (See page 1641, col. 2-page 1644, col. 2, last paragraph). Remington also teaches compressible sugars such as lactose, sucrose, and starch can be used for direct compression (See page 1645, col. 2, last paragraph).
>
> It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ wet and dry granulation method and incorporate a compressive agent into the method of Heinemann et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a tablet by further compressing the resulting composition of Heinemann et al.
>
> One of ordinary skill in the art would have been motivated to employ wet and dry granulation method and incorporate a compressive agent into the method of Heinemann et al. because the wet and dry granulation and incorporating compressive agents are well-known in the art to be useful for formulating a tablet. Employing well-known method and excipients in formulating pharmaceutical composition would be obvious as being within the purview of skilled artisan.
>
> One of ordinary skill in the art would have been motivated to prepare a tablet by further compressing the resulting composition of Heinemann et al. After the volatile solids are removed, the composition become porous. Because of the porous nature of the resulting composition, further compression can be applied which would be reasonably expected to make the tablet more compact and stronger thereby.

The rejection is traversed on the basis that it is based on hindsight, and on the fact that applying Applicant's teachings to Heinemann, or vice-versa, would defeat the purpose of the other. The device/dosage form of Heinemann is different in purpose and structure from the dosage form/device claimed by Applicant. Because of this, applying Remington's teachings to Heinemann would likely destroy Heinemann.

Heinemann discloses a process for the preparation of porous tablets. Heinemann discusses his process in summary form at column 1, lines 58-65, and the following several paragraphs:

> In accordance with the present invention, the conventional process of mixing tablet components and pressing the mix into predetermined shape is modified by incorporating into the mix at least one inert readily volatilizable solid adjuvant, pressing the mix into shape, and thereafter volatilizing the adjuvant, whereby the resulting tablets are porous, strong, shape retaining and readily disintegrable. [column 1, lines 58-65]
>
> ...Therefore, when the adjuvant is removed, it leaves behind comparatively large hollow spaces and canals, through which solvent can penetrate. [column 2, lines 4-6]

From the above disclosure in Heinemann, it is clear that Heinemann's finished device is meant to contain "spaces and canals" as an integral component therein. Heinemann in fact clearly states that it is an object of his invention to produce "...readily dissolved, porous tablets in conventional tablet presses..."[column 1, lines 54-56]. This is in distinct contrast to Applicant who requires a final compression step, which would destroy Heinemann's spaces and canals.

Applicant's process could not be used to make a device as disclosed in Heinemann. That is because Applicant's process, as defined in claim 1, claims a compression step following the step in which a porous second granulate is made (i.e., as the result of volatilizing a solid volatilizable agent from first granules). The compression step follows, with the granules being compressed into a tablet-like dosage form or compressed device. Application of such a compression step as the last step in Heinemann would likely destroy Heinemann's device by

collapsing the "spaces and canals" that Heinemann specifically teaches incorporating into his product.

Likewise, one of ordinary skill in the art would not find it obvious to combine compression as disclosed in Remington with the process disclosed in Heinemann. Combining a compression step as taught by Remington with a pore-creating step as taught by Applicant, and in the same order required by Applicant's claim 1, would not result in a Heinemann device because Heinemann's spaces and canals would collapse from being compressed, thereby defeating the purpose of Heinemann's invention.

Remington contains no teachings otherwise which would remedy the defects in Heinemann. Remington simply discloses that various granulation and compression methodologies are known. It would not be obvious, however, to apply the teachings of Remington to Heinemann for the reasons stated above - - applying teachings relating to compression to Heinemann would destroy the device that Heinemann discloses and claims.

So far as claims 33-37, which relate to granules, are concerned, they are not rendered obvious by Heinemann, Remington, or any combination thereof either. Applicant's claimed granules are porous, the porosity imparting improved compressive properties (such as hardness or tensile strength) to the device which results from compressing the granules. However, the very act of compression which enhances the resulting tablets' compressive properties, destroys the porosity of the granules. The resulting compressed device, although having enhance compressive properties such as tensile strength and hardness, loses its porosity from the act of compression. Although Heinemann discloses a finished device which has "spaces and pores", Heinemann does not disclose or suggest a porous granulate, nor any way to make one. Nor does Remington. Applicant's porous granules simply cannot be obvious over references which mention nothing about them.

With respect to claim 38, Applicant's arguments from above relating to claims 1-32 are incorporated herein by reference. In brief, neither Heinemann nor Remington disclose a means or suggest any reason for preparing a compressed device resulting from compressing porous granules from which a solid volatilizable agent has been volatilized. That act of compression destroys

the pores and channels in such granules in favor of a compressed device, such as a tablet, having improved compressive properties.

In summary, Applicants' claimed method for forming a device in which the pores have been compressed cannot be obvious from Heinemann who discloses spaces and canals as an integral part of his final product. The law is equally clear on this point. That is, in order for an obviousness rejection to lie, the prior art must in some way supply a suggestion to do that which Applicant has invented, and must also provide a reasonable expectation of success. . American Hospital supply Corp. v. Travenol Laboratories, Inc., 223 USPQ 577, 582 (Fed. Cir. 1984). The Federal Circuit has explained the proper test:

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out **and would have a reasonable likelihood of success**, viewed in light of the prior art. **Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure** (emphasis added).

In re Dow Chemical Co., 5 USPQ.2d 1529, 1531 (Fed. Cir. 1988); Amgen, Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ.2d 1016. 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). Since Heinemann, alone or in combination with Remington, suggests neither porous granules nor the compressed product made therefrom, the obviousness rejection should be withdrawn.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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VERSION MARKED UP TO SHOW CHANGES MADE

1. (Once Amended) A method for preparing a pharmaceutical dosage form comprising:

forming first granules comprising a solid pharmaceutically acceptable volatilizable agent and a pharmaceutically active ingredient by a granulation method selected from a wet granulation method and a dry granulation method;

volatizing the solid volatilizable agent from the first granules to form a second granule; followed by

compressing the second granules to form a pharmaceutical dosage form.

33. (Once Amended) Pharmaceutical granules ~~having enhanced compressive properties~~ prepared by a method comprising:

forming first granules comprising a solid pharmaceutically acceptable volatilizable agent and a pharmaceutically active ingredient by a granulation method selected from a wet granulation method and a dry granulation method; and

volatizing said volatilizable agent from the first granules to form pharmaceutical granules.

38. (Once Amended) A method for preparing a compressed device comprising:

forming first granules comprising a solid volatilizable agent and an active ingredient;

volatizing the solid volatilizable agent from the first granules to form second granules; followed by

compressing the second granules to form a compressed device.